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10/563,278	10/06/2006	Jacques Abraini	Serie 6132	6401

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EXAMINER	
ARNOLD, ERNST V	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,278	ABRAINI ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-53* is/are pending in the application.

4a) Of the above claim(s) *31-42 and 50-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 have been cancelled. Claims 31-53 are new. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8/25/08 as well as amendments prompted the new ground(s) of rejection presented in this Office action.

Newly submitted claims 31-42 and 50-53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 31-42, drawn to drawn to a process for preventing or treating a neurointoxication.

Group II, claim(s) 43-49, drawn to a gaseous inhalable medicament for the prevention or treatment of addiction.

Group III, claim(s) 50-52, drawn to a process for preventing or treating addiciton.

Group IV, claim(s) 53, drawn to a process for the manufacture of all or part of an inhalable medicament.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

technical features for the following reasons: It appears that the special technical feature is a gaseous mixture comprising from 5 to 35% by volume xenon and from 10 to 50% by volume nitrous oxide. However, this technical feature is already disclosed in the art. Mondain-Monval (US 4,820,258) disclose gaseous mixtures containing from about 50 to 80% by volume nitrous oxide; at least about 20% by volume oxygen and an inert gas; xenon (Claims 1-5). Thus by simple arithmetic, the disclosure of Mondain-Monval embraces a gaseous mixture of 50% by volume nitrous oxide; 20% by volume oxygen and 30 % by volume xenon. Since the special technical feature is already disclosed in the art then it does not contribute to the art and restriction is deemed proper. The intended use of the composition is not a distinguishing feature because such a use is inherent in the composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-42 and 50-53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn rejections:

Applicant's amendments and arguments filed 8/25/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Information Disclosure Statement

Foreign language documents have been considered to the extent that an English language Abstract; international search report in English or English language translation has been provided. Otherwise a line has been drawn through the reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-47 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, ***while being enabling for treating drug addiction***, does not reasonably provide enablement for prevention or treatment of any and all addictions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

Let the Examiner be clear: Applicant is not enabled for prevention and treatment of any and all addictions.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of

the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that exposure to xenon or nitrous oxide immediately after pretreatment with d-amphetamine induces dose-dependent blocking of the sensitization process (specification page 10, lines 34-37 and specification page 11, lines 13-29, 35 through page 12, line 9). However, Applicant is purporting to prevent and treat any and all addictions.

2) Nature of the invention

The nature of the invention is directed to gaseous compositions comprising xenon and nitrous oxide.

3) Relative level of skill possessed by one of ordinary skill in the art

MPEP 2141.03 states (in part), "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 167 LEd2d 705, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary

skill in the art would employ." Id. At 1396, 82 USPQ2d at 1396. The "hypothetical person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." Ex parte Hiyamizu, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.). (emphasis added).

4) State of, or the amount of knowledge in, the prior art

The art teaches that administration of xenon to treat neurointoxications (Petzelt et al. (WO 00/53192). Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic.action of N-methyl-D-aspartate (reference C7 on the IDS submitted on 10/06/06) David et al. teach and suggest combining xenon and nitrous oxide to obtain optimal subcortical neuroprotection while minimizing the risk of adverse side effects and that the combination could be used in other brain diseases (reference C3 on the IDS submitted on 10/06/06).

5) Level or degree of predictability, or a lack thereof, in the art

There are different types of addictions which require different treatments and have different expected outcomes.

The art teaches that **pathological gambling** is an addiction (medical encyclopedia: pathological gambling; page 1 of 3).

The art teaches that **alcoholism** is a type of drug addiction (medical encyclopedia: alcoholism; page 1 of 3).

The art teaches that **sexual addiction** is yet another form of addiction (Abstract: Bancroft et al. J. Sex Res 2004, 41(3), 225-34).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. The specification does not guide or provide direction for preventing or treating all forms of addiction.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to preventing or treating all forms of addiction. The specification is limited to describing exposure to xenon or nitrous oxide immediately after pretreatment with d-amphetamine induces dose-dependent blocking of the sensitization process (specification page 10, lines 34-37 and specification page 11, lines 13-29, 35 through page 12, line 9)..

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising administration of a gaseous mixture to individuals who either have physiological

addictions to drugs or other physchological addictions with the hopes that the composition will perform as instantly claimed. Essentially, one of ordinary skill in the art has to figure out how to do this themselves. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to see if this invention is enabled.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." (Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 42, 43, 46 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Homi et al. (Anesthesiology 2003, 99,876-881).

Homi et al. provide gaseous compositions and methods of administrating the gas to a subject (See: Materials and Methods page 876). Homi et al. administered three gas mixtures to mice subjected to 60 minutes of middle cerebral artery occlusion: 1) 70% xenon and 30% oxygen; 2) 70% nitrous oxide and 30% oxygen; and 3) **35% xenon and 35% nitrous oxide and**

30% oxygen (Page 877, left column, last paragraph; page 878, under results; Table 2, page 878 upper right and corner and Figure 1, page 879, for example). It is the Examiner's position that 35% is "about 30%" of instant claim 46.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, preventing or treating addiction, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Response to arguments:

Applicant asserts that Homi is not prior art. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43, 44 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Mondain-Monval (US 4,820,258).

Mondain-Monval disclose gaseous mixtures containing from about 50 to 80% by volume nitrous oxide; at least about 20% by volume oxygen and an inert gas; xenon (Claims 1-5). Thus one of ordinary skill in the art can immediately envision a gaseous mixture of **50% by volume** nitrous oxide; 20% by volume oxygen and **30 % by volume xenon**.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, preventing or treating addiction, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Response to arguments:

Applicant asserts that the gas mixture of Mondain-Monval is for a different purpose. As stated above, the intended use of the composition is not distinguish the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art

to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 43-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lecourt et al. (US 2002/0033174) in view of Petzelt et al. (WO 00/53192) and Jevtovic-Todorovic et al. (reference C7 on the IDS submitted on 10/06/06) and Brooks (US 5846556).

Applicant claims a gaseous inhalable medicament for the prevention or treatment of addiction, wherein the medicament comprises from 5% to 35% by volume of xenon and from 10% to 50% by volume of nitrous oxide.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Lecourt et al. teach an inhalable medicament intended for the treatment of pain with a therapeutically effective amount of a mixture of several gases chosen from helium, oxygen, nitrogen, xenon, hydrogen, carbon monoxide, carbon dioxide, argon, krypton, nitrogen monoxide, nitrous oxide, carbonated hydrocarbons and fluorocarbons (Abstract and claims 13

and 14). Therefore, it is the Examiner's position that all possible proportions of gases that are therapeutically effective are embraced by Lecourt et al.

Petzelt et al. teaches preparation of gaseous mixtures of xenon with 5 to 90% by volume xenon and further contains oxygen and/or nitrogen and/or air (Claims 12-15). Petzelt et al. suggest mixing xenon with other gases harmless for humans (page 6, middle of page). Petzelt et al. teach the use of the gas mixture for treating apoplexy (stroke) and craniocerebral trauma (claims 1, 4 and 8).

Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic.action of N-methyl-D-aspartate (Right column, page 460). Jevtovic-Todorovic et al. treated adult rats with various gas mixtures of nitrous oxide and oxygen ranging from 20%, 40%, 80%, 150% and 180% nitrous oxide, for example (Page 462, top left column and page 463, methods). Jevtovic-Todorovic et al. suggest that administration of nitrous oxide may provide neuroprotection against cerebral ischemic events that sometimes accompany surgery (Page 463, left column).

Brooks teaches compositions with 0-30 % nitrous oxide (column 2, lines 34-37).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Lecourt et al. is that Lecourt et al. do not expressly teach the instantly claimed amounts of xenon and nitrous oxide in the composition This deficiency in Lecourt et al. is cured by the teachings of Petzelt et al., Brooks and Jevtovic-Todorovic et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Lecourt et al. with 5-35% xenon and from 10 to 50% nitrous oxide; or a composition of xenon and nitrous oxide of about 30%; or composition with 20 to 32% by volume xenon and from 20 to 40% of nitrous oxide; or a composition from 10 to 20 % by volume xenon and from 45 to 50% of nitrous oxide or a volume proportion of xenon of about 16% and a volume proportion of nitrous oxide of about 50%, as suggested by Petzelt et al., Brooks and Jevtovic-Todorovic et al.

One of ordinary skill in the art would have been motivated to do this because: 1) Lecourt et al. suggest mixtures of gases but only teaches a therapeutically effective amount and one of ordinary skill in the art would select xenon and nitrous oxide for mixing because the invention of Lecourt et al. is directed towards treating pain the anesthetic/analgesic gases nitrous oxide and xenon stand out amongst the other gases for that selection; and 2) the cited references teach a wide range of gas amounts to use and it is then merely routine optimization of those amounts to arrive at the instant invention. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant's arguments are moot in view of the new ground of rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst V Arnold
Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616